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**Sydney, Australia**

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## **ASX: NOX**

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## **DARRT-1 Study Fully Enrolled**

- **Final patient enrolled into study**
- **Topline data to be announced in Q4 2019**

**SYDNEY, 30 May 2019:** Noxopharm (ASX: NOX) ('**Noxopharm**' or the '**Company**') is pleased to announce that the DARRT-1 study, investigating Veyonda<sup>®</sup> in combination with low dose external beam radiotherapy in men with late-stage, metastatic, castration-resistant prostate cancer (mCRPC), has completed enrolment. This is the company's first clinical study of the Company's external beam radio-enhancement program (DARRT).

The DARRT treatment regimen is a novel approach to the treatment of mCRPC that the Company believes, if successful, will be a transformative treatment option for this cancer where none currently exists. The regimen used in DARRT-1 involves administering a short course (15 days) of Veyonda<sup>®</sup> (which enables the active ingredient to be supplied to all tumours with an adequate blood supply) and then applying a palliative (low) dose of radiation to a single lesion. The aim of this combination is to trigger an immune response in the irradiated lesion that then spreads to other lesions that are not irradiated. The treatment regimen for DARRT-1 is designed to be of short duration, minimally invasive, well tolerated, and readily available in most hospitals.

As previously announced, the DARRT-1 study is being conducted in 2 stages (dose escalation stage and dose expansion stage). The dose escalation stage, with cohorts of 4 men receiving different dosages of Veyonda<sup>®</sup> (400, 800 and 1200 mg daily for 15 days) has been completed and results have been announced for the 3-month and 6-month post treatment assessments, showing encouraging evidence of durable clinical responses. The 1200 mg Veyonda<sup>®</sup> dose was selected for the dose expansion phase.

Enrolment of the dose expansion phase closed with enrolment of the 12th patient, meeting the target number of patients in this phase. The patients are being followed-up at regular intervals for clinical assessments of response based on two main measures (i) pain levels, where reduction of  $\geq 30\%$  compared to baseline is considered to represent significant pain relief, and (ii) PSA (prostate specific antigen) levels, where falls in PSA levels of  $\geq 50\%$  compared to baseline are considered to be a clinical response. Where possible, objective tumour responses (number and size of lesions) by scanning will be conducted as per RECIST 1.1 guidelines.

The Company had anticipated this trial being fully enrolled in March but extended the enrolment time in order to ensure that the eligibility criteria were met as per protocol. The Company is grateful for the ongoing support of the investigators and for the participation of the patients.

The Company will perform a preliminary analysis of safety and efficacy once the last patient in stage 2 has reached the 3-month mark in the study. This data is expected to be released in August 2019. The 6-month mark will be reached in November 2019, with the topline data expected to be released at that time. The company aims to present the full data at an international scientific congress in H1 2020.

### **About Veyonda®**

Veyonda® (previously known as NOX66) is an innovative dosage formulation of the experimental anti-cancer drug, idronoxil, developed specifically to enhance the anti-cancer activity of idronoxil. Idronoxil inhibits the oncogene, Ecto-NOX disulfide-thiol exchanger type 2, leading to inhibition of the key secondary pro-survival messenger, sphingosine-1-phosphate. This enhances the DNA-damaging effects of radiotherapy and cytotoxic chemotherapy, as well as activating the body's innate immune system.

### **About the DARRT program:**

The Company's DARRT (Direct and Abscopal Response to Radiotherapy) Program is testing the ability of Veyonda® to increase tumour response to palliative dosages of radiotherapy. The rationale of DARRT is to combine the radio-enhancing properties of Veyonda® that stem from its inhibition of sphingosine-1-phosphate pro-survival functions, combined with its ability to stimulate the body's first line immune defence cells against cancer. The clinical outcome being sought is greater shrinkage of irradiated tumours and shrinkage of non-irradiated tumours (abscopal response). The DARRT treatment regimen is being tested initially in prostate cancer, but in due course is to be extended into other forms of solid cancer that the Company believes will assist the Veyonda® marketing approval process.

### **About DARRT-1**

DARRT-1 is a Phase 1b 24-subject study being conducted in Georgia and Australia. The DARRT-1 treatment regimen entails a 5-day course of radiotherapy (20-30 Gy) in 5 fractionated dosages targeting a single tumour, with Veyonda® administered daily for 13-16 days. The study is in 2 arms, each with 12 subjects. The first arm is for dose-finding entailing 3 cohorts of 4 subjects receiving 400 mg, 800 mg and 1200 mg Veyonda® respectively. In the second arm, an additional 12 subjects are receiving the 1200 mg Veyonda® dose. The subjects are being assessed clinically at 6-, 12- and 24- weeks.

### **About Noxopharm**

Noxopharm is a clinical-stage Australian drug development company with offices in Sydney and New York. The Company has a primary focus on the development of drugs based on a phenolic chemical structure, with Veyonda® the first pipeline product. The pipeline includes a number of other drug candidates for both oncology (within NOX) and non-oncology indications (in subsidiary company, Nyrada Inc).

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